

## UNIVERSITY OF CALIFORNIA, SAN FRANCISCO CONSENT TO PARTICIPATE IN A RESEARCH STUDY

**Study Title:** Comparison of the effects of oral psilocin, sublingual psilocin, and oral psilocybin in healthy adults

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This is a clinical research study about the effects of psilocin versus psilocybin. The study team leader is Josh Woolley M.D., Ph.D., from the UCSF Department of Psychiatry & Behavioral Sciences. A trained member of the study team will explain the study and discuss it with you. You can ask the team member questions at any time.

### **STUDY SUMMARY**

**Introduction:** We are asking you to consider taking part in a research study being done by a team of doctors and scientists led by Dr. Josh Woolley, M.D., Ph.D., at UCSF.

The first part of this consent form gives you a summary of this study. We will give you more details about the study later in this form. The study team will also explain the study to you and answer any questions you have.

**Purpose of the study:** The purpose of this study is to compare the effects of hallucinogenic mushrooms (psilocybin) to the effects of the substance that psilocybin is broken down into after ingestion. This substance is called psilocin. Psilocin is the active component of ingested psilocybin and is believed to be responsible for its effects, including alterations in perception, mood, consciousness, cognition, or behavior. Administration of psilocin may lead to more consistent beneficial effects and have fewer negative effects compared to psilocybin. We will evaluate the effects of psilocin using oral and under the tongue (sublingual) administration. We will test this hypothesis in healthy adults.

You are being asked to participate because you are a healthy volunteer.

**Study Procedures:** If you choose to be in this study, you will complete several screening procedures to confirm your eligibility. This process may take up to 30 days. After eligibility is confirmed, you will complete four drug dosing sessions, including administration of 1) oral

psilocin, 2) sublingual psilocin, 3) a second sublingual psilocin dose, and 4) oral Psilocybin. Each dosing session will be 8 hours.

You will undergo a preparatory informational session (2-3 hours) before beginning drug dosing sessions, each of which will be followed by an integration session (1-2 hours). A preparatory session is where you meet with a facilitator (trained therapist) to prepare for the drug experience, by discussing expectations, practicing therapeutic touch, and listening to music. An integration session is where you meet with the same facilitator the morning after your drug experience to discuss how the session went for you and any side effects you experienced after or are currently experiencing. After completion of dosing and integration, you will complete a follow-up phone call, including several questionnaires. Follow-up will occur 30 days after completion of each dosing session and before proceeding to the next dosing session. In total, you will be in the study for 4-6 months and visit the research site approximately 10 times.

**Possible Risks:** There are risks to taking part in a research study. The most likely risks of psilocin and/or psilocybin in the hours after you take it include:

- Nausea
- Blurred vision and dilated pupils
- Headache
- Mild to moderate increase in heart rate and blood pressure
- Anxiety and fear

We will tell you more about these risks and other risks of taking part in the study later in this consent form. There may also be risks that we do not know about.

**Possible Benefits:**

There will be no direct benefit to you from participating in this study. However, you may enjoy the feeling of contribution to knowledge in the health or social sciences field.

**Your Other Options:** You do not have to participate in this study. Your other choices may include:

- Taking part in another study.
- Not taking part in a study.

Feel free to talk to your doctor about your choices before agreeing to participate in this study.

Following is a more complete description of this study. Please read this description carefully. You can ask any questions you want to help you decide whether to join the study. If you join this study, we will give you a signed copy of this form to keep for future reference.

## **DETAILED STUDY INFORMATION**

This part of the consent form gives you more detailed information about what the study involves.

Research studies include only people who choose to take part. Please take your time to make your decision about participating and discuss your decision with your family or friends if you wish. If you have any questions, you may ask the researchers.

You are being asked to take part in this study as a healthy volunteer.

### **Why is this study being done?**

The purpose of this study is to compare the effects of ingested psilocybin to the substance that it is broken down into, called psilocin. Psilocin is the active substance of psilocybin, which goes into effect once psilocybin is digested. While oral psilocybin has been studied in many clinical trials, directly administered psilocin taken by mouth (orally) or under the tongue (sublingual) has not. The study team is investigating whether psilocin may lead to more consistent beneficial effects and have fewer negative effects compared to psilocybin. Psilocin is a controlled substance without an approved use.

### **Who pays for this study?**

Filament Ventures, a for-profit psychedelic science organization, is funding this study. The study leader, Josh Woolley, MD, PhD, is a doctor and faculty member employed by UCSF. Dr. Woolley will not receive any compensation from Filament Ventures beyond his regular salary from UCSF and the San Francisco Medical Center (SFVA). The drugs being tested in this study, psilocin and psilocybin, will be provided by researchers at Filament Ventures. Filament Ventures has patents pending related to the formulations used in the current study.

### **Disclosure of financial or proprietary interests:**

The investigators have the following disclosures related to this study:

**Josh Woolley:** Compensated consultant on the Scientific Advisory Board of Silo Pharma. Silo Pharma is a for-profit company interested in developing psilocybin as an available therapy. They fund clinical trials designed to study psilocybin's effects in different patient populations. Dr. Woolley consults on the development of new studies for Silo Pharma.

### **How many people will take part in this study?**

20 healthy volunteers will participate in this study.

### **What will happen if I take part in this research study?**

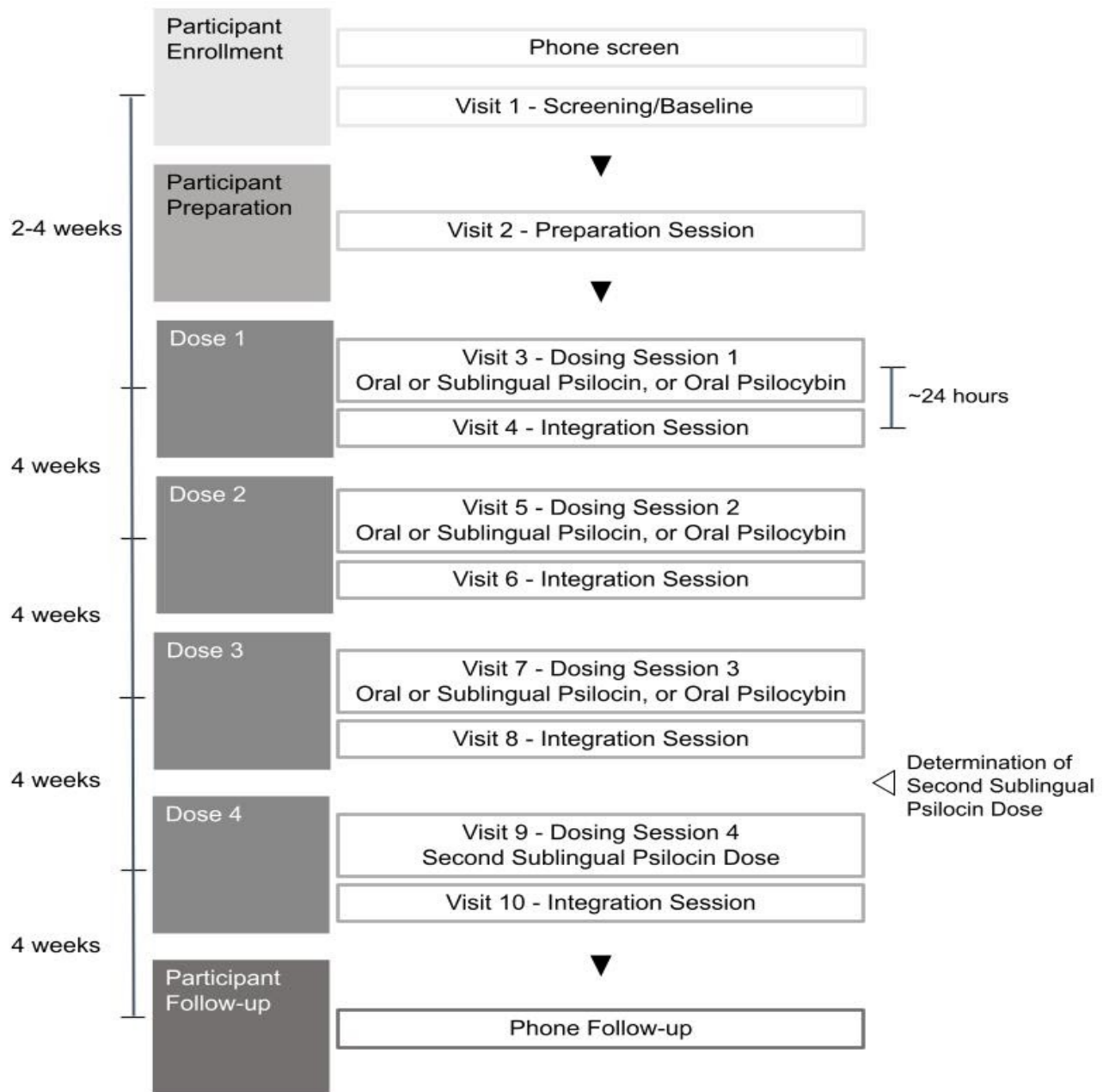
First, you will provide informed consent by reviewing this document with the study team and providing your signature. Consent will either be obtained remotely using DocuSign, or in-person before you begin any study procedures, depending on the state of the COVID-19 pandemic. If remote, this will occur over a Zoom call. If in person, you will be consented in our research unit at Langley Porter Psychiatric Institute.

After consenting, you will complete a series of assessments in-person and by video to confirm your eligibility for this study. This may take 2-3 hours in total. If you are eligible, you will meet

with a facilitator one-on-one and complete an in-person, informational preparatory session, at our research unit located in UCSF Langley Porter Psychiatric Institute (LPPI; 401 Parnassus Ave, San Francisco, CA). This will last 2-3 hours. After preparation, you will complete your first in-person dosing session at our research unit. For each dosing session, your dose will be assigned in a random order. Before your dosing session, you will be asked to provide the name and contact information for your designated support person, who will escort you home on the evening of your dosing session. This session will last approximately 8 hours. Your facilitator will be present all day, and one of our study physicians will be available at all times. The morning after your dosing session, you will complete an integration session with your facilitator, in person or by video, lasting 1-2 hours. For the duration of the COVID-19 pandemic, integration sessions will be conducted remotely over Zoom, unless an in-person session is necessary for your safety. As the pandemic recedes, sessions may be conducted in person. The study team will communicate with you about these changes and take into account your level of comfort with in-person activity. Integration sessions will be audio and video recorded. 4 weeks after your first dosing session, and before additional dosing, you will complete a follow-up survey by phone. You will complete this survey 4 weeks after every dosing session, and before moving onto additional dosing. This can be completed in-person or remotely and will take approximately 1 hour.

A minimum of 4 weeks after your first dosing session, you will return to our research unit for a second dosing session (in-person, 8 hours), followed by a second integration session (remote or in-person, 1-2 hours). A minimum of 4 weeks later, you will return for your third dosing session (in-person, 8 hours), followed by a third integration session the day after (remote or in-person, 1-2 hours). Finally, at a minimum of 4 weeks after your third dosing session and upon PI's confirmation of safety and tolerability, you will return to our research unit for a fourth dosing session (in-person, 8 hours), followed by a final, fourth integration session the day after (remote or in-person, 1-2 hours). You will only complete a fourth dosing session if the PI determines it is safe to do so. 30 days after your last integration session, you'll be contacted by phone to check for any negative effects you might have noticed since your last study visit and complete several questionnaires. This will take 20-30 minutes.

## FLOWCHART OF STUDY PROCEDURES:



If you agree, the following procedures will occur:

**Screening / Baseline Sessions (\*Combination of remote and in-person activity):**

You will need to complete the following exams, tests or procedures to confirm you are eligible for this study. These exams, tests or procedures are part of regular medical care and may be done even if you do not decide to join the study. If you have had some of them recently, you may not need to repeat them. This will be up to your study doctor. These can be broken into multiple visits if necessary.

Procedures that can be conducted remotely, such as clinical interviews, questionnaires, and medical history, will be performed remotely via Zoom during the COVID-19 pandemic. Certain procedures require in-person activity, including the physical exam, blood draws, and urine tests. As the pandemic recedes, all session procedures may be conducted entirely in-person. The study team will communicate with you about these changes.

- Questions about your general health and medical history, including your mental health
  - You will be asked sensitive questions, such as about past substance use
- Physical exam and vital signs
- Electrocardiogram (ECG) where stickers will be placed on your body to detect the electric activity in your heart
- Blood draw where a needle will be inserted into a vein in your arm. A total of about 5 tablespoons of blood will be drawn for tests.
- Urine tests, including a urine drug screen for recent drug use and pregnancy test (if you can become pregnant).
  - The following substances will be tested in the urine drug screen: amphetamines, benzodiazepines, cocaine, cannabis, MDMA, and opioids (including methadone and buprenorphine)
- You will be asked to provide the name and contact information for your designated support person who will take you home after your dosing session.

**Before the first psilocybin session:**

If the exams, tests and procedures show that you can continue to be in the study and you choose to take part, then you will complete the following in-person / video sessions and procedures:

- One preparation session with your facilitator. This will be in person. We will familiarize you with what to expect during your psilocybin session including the physical space where you will take psilocybin.

**First dosing session (\*In-person required):**

- You will arrive at our research unit around 8:00 am.
- Before taking psilocybin and/or psilocin, study staff will put your belongings (e.g. phone, wallet, keys) in a secure location. This is to ensure your safety while you are on psilocybin. Items will be returned to you once the effects of psilocybin have worn off, after about 6 hours.
- You will be asked to complete urine tests, including a urine drug screen for recent drug use and pregnancy test (if you can become pregnant), and a breathalyzer test.
- During this visit, you will be randomly assigned to receive oral psilocin 17.5 mg, sublingual psilocin 2.18 mg, or oral psilocybin 25 mg.
- You will take both an oral capsule and a tablet under your tongue. One of these substances will be placebo (an inactive substance), and the other will be active drug. The purpose of this procedure is so that neither you nor the research team knows which substance is the active drug.
- While you are on study drug, your facilitator will monitor your heart, blood pressure, temperature, and how you are feeling. A study physician will be available at all times.
- After drug effects have worn off, you will complete several self-report questionnaires.
- Following completion of questionnaires, study staff will confirm that you are ready to safely leave the research unit.
- Your designated support person will meet you at our research unit and escort you home. This is for your safety, because you should avoid operating heavy machinery, driving home, etc.
- The following morning, the study team will check in with you about any side effects you might have experienced.

**First integration session (\*Remote for the duration of the COVID-19 pandemic; can be in-person if the study team determines this is necessary for your safety. As the pandemic recedes, this visit may be conducted in-person. The study team will communicate with you about these changes):**

- The morning after your first dosing session, you will complete your first integration session with the study facilitator.
- You will be asked to report any dosing-related side effects.
- Next, you will be asked and encouraged to share about their dosing session experience with the facilitator.
- All integration sessions will be audio and video recorded to ensure treatment fidelity and for subsequent behavioral analyses.



**Follow-up Surveys (\*Remote):**

- One month after your first dosing session, and before moving onto additional dosing sessions, you will complete several questionnaires.
- Surveys can be completed in-person or remotely.

**Second dosing session (\*In-person required):**

- At a minimum of 4 weeks following your first dosing session, you will return to the UCSF facility for a second dosing session. The procedure will be the same as in the first dosing session.
- You will be randomly assigned to receive oral psilocin 17.5 mg, sublingual psilocin 2.18 mg, or oral psilocybin 25 mg.
- You will take both an oral capsule and a tablet under your tongue. One of these substances will be placebo (an inactive substance), and the other will be active drug. The purpose of this procedure is so that neither you nor the research team knows which substance is the active drug.
- Your designated support person will meet you at our research unit and escort you home. This is for your safety, because you should avoid operating heavy machinery, driving home, etc.

**Second integration session (\*Remote for the duration of the COVID-19 pandemic; can be in-person if the study team determines this is necessary for your safety. As the pandemic recedes, this visit may be conducted in-person. The study team will communicate with you about these changes):**

- The morning after the second dosing session, you will complete the second integration session with the study facilitator. The procedure will be the same as in the first integration session.
- Session will be audio and video recorded.

**Follow-up Surveys (\*Remote):**

- One month after your second dosing session, and before moving onto additional dosing sessions, you will complete several questionnaires.
- Surveys can be completed in-person or remotely.

**Third dosing session (\*In-person required):**

- At a minimum of 4 weeks following your second dosing session, you will return to the UCSF facility for a third dosing session. The procedure will be the same as in the first dosing session.



- You will be randomly assigned to receive oral psilocin 17.5 mg, sublingual psilocin 2.18 mg, or oral psilocybin 25 mg.
- You will take both an oral capsule and a tablet under your tongue. One of these substances will be placebo (an inactive substance), and the other will be active drug. The purpose of this procedure is so that neither you nor the research team knows which substance is the active drug.
- Your designated support person will meet you at our research unit and escort you home. This is for your safety, because you should avoid operating heavy machinery, driving home, etc.

**Third integration session (\*Remote for the duration of the COVID-19 pandemic; can be in-person if the study team determines this is necessary for your safety. As the pandemic recedes, this visit may be conducted in-person. The study team will communicate with you about these changes):**

- The morning after the third dosing session, you will complete the third integration session with the study facilitator. The procedure will be the same as in the first integration session.
- Session will be audio and video recorded.

**Follow-up Surveys (\*Remote):**

- One month after your third dosing session, and before moving onto your final dosing session, you will complete several questionnaires.
- Surveys can be completed in-person or remotely.

**Fourth dosing session (\*In-person required):**

- At a minimum of 4 weeks following your third dosing session, you may return to the UCSF facility for your fourth and final dosing session. The procedure will be the same as in the first dosing session.
- Depending on the PI's assessment of your tolerability of 2.18mg sublingual psilocin, you may receive a second sublingual psilocin dose of 4.36mg.
  - If the PI determines it is unsafe to proceed with a 4.36mg dose, you will not complete a fourth dosing session.
- You will take both an oral capsule and a tablet under your tongue. One of these substances will be placebo (an inactive substance), and the other will be active drug. The purpose of this procedure is so that neither you nor the research team knows which substance is the active drug.
- Your designated support person will meet you at our research unit and escort you home. This is for your safety, because you should avoid operating heavy machinery, driving home, etc.

**Fourth integration session (\*Remote for the duration of the COVID-19 pandemic; can be in-person if the study team determines this is necessary for your safety. As the pandemic recedes, this visit may be conducted in-person. The study team will communicate with you about these changes):**

- The morning after your fourth dosing session, you will complete your final integration session with the study facilitator. The procedure will be the same as in the first integration session.
- Session will be audio and video recorded.

**Phone Follow-Up (\*Remote):**

- One month after your final dosing session, you will be contacted by phone to check for any negative effects you may have noticed since your last study visit.
- You will also complete several questionnaires.

**Audio-video recording**

We will be audio and video recording you during this study. We will use these recordings to make sure our study staff meet quality requirements, and to perform behavioral analyses. We will protect the confidentiality of all recordings by limiting access to them. Only study team members and researchers who are analyzing data from this study will be able to access the recordings. The recordings will be stored on encrypted computer drives that are kept in locked rooms at UCSF. They will be kept permanently and securely by the UCSF Department of Psychiatry and Behavioral Sciences.

We may share recordings with researchers at our university/other universities who are collaborating with us, or companies that are helping with data analysis (for example, we may have a HIPAA-compliant, secure service transcribe audio recordings to text). Any data transferred outside of UCSF will involve a legally binding, signed agreement to make sure that collaborators use appropriate procedures to protect your privacy. We will not share your name or any additional personal information. When possible, we will only share de-identified data. Any data that we share with collaborators will be destroyed when we finish the analysis. Your data, including audiovisual recordings, will never be accessible to the general public.

**How long will I be in the study?**

You will be in the study for up to 6 months. Expected length of participation is 4-6 months, or approximately 50 hours. This includes:

- Screening: 2-3 hours; can take up to 30 days
- Treatment: one preparatory session (2-3 hours), four dosing sessions (8-hours), four integration sessions (1-2 hours), and four follow-up surveys (1 hour).
- Follow-up: 30 days (30 minutes)

## **Can I stop being in the study?**

Yes. You can decide to stop at any time. If you are thinking about stopping or decide to stop, the study team leader will work with you to make sure that you are able to stop your participation safely.

**Important Note:** While you are under the effects of psilocybin and/or psilocin (which last about 5-6 hours), you will not be able to stop being in the study. If you tell a study doctor, your facilitators, or another study staff member that you wish to stop being in the study, you will still have to stay at the research unit until the drug effects have worn off and it is safe for you to leave. This is because we must prioritize your safety while you are under the effects of psilocybin.

It is important to tell a study doctor if you are thinking about stopping so any risks from the psilocybin dose can be monitored.

One of the study doctors may stop you from taking part in this study at any time if they believe it is in your best interest, if you are not able follow the study rules, or if the study is stopped.

## **What side effects or risks can I expect from being in the study?**

You may have side effects while on the study. The study staff will monitor you for any side effects. However, doctors don't know all the side effects that may happen. Side effects may be mild or very serious. Your health care team may give you medicines to help lessen side effects. Many side effects from psilocybin and/or psilocin go away soon after the session ends. In some cases, side effects can be serious, long lasting, or may never go away.

You should talk to a study doctor about any side effects you experience while taking part in the study.

Please note, there are some unknown side effects of sublingual administration, as there are no previous published studies on this method.

Medical risks and side effects related to taking psilocybin and/or psilocin include those which are:

### **Likely**

- Temporary elevations in heart rate and/or blood pressure during the drug session
- Temporary anxiety or confusion during the drug session
- Headache soon after the drug session

### **Less Likely**

- Nausea and/or vomiting during the drug session
- Temporary slower movements or difficulty coordinating movements during the drug session
- Temporary fatigue or difficulty sleeping the night after the drug session

### **Rare but serious**

- Elevated blood pressure during the drug session that require medications to bring back to normal
- Elevated body temperature, muscle stiffness, and confusion during the drug session due to serotonin syndrome (too much serotonin in the body)
- Anxiety, mania (elevated arousal, affect, and energy level), or psychotic symptoms (like hallucinations or paranoia) soon after the drug session that last for >24 hours after the drug wears off
- Anxiety, mania or psychotic symptoms during or after the drug session that are severe and require medications to maintain your safety and/or the safety of study staff
- Unknown Risks: It is important to note that psilocybin and/or psilocin may have side effects that no one knows about yet. The study leaders will let you know if they learn anything that might make you change your mind about participating in the study.

### **Other risks of participating in this study**

- Blood Drawing (Venipuncture): Drawing blood may cause temporary discomfort from the needle stick, bruising, infection, and fainting.
- Reproductive risks: The drugs [or procedures] in this study can affect an unborn baby or infant. You should not become pregnant, breastfeed, or [if required] father a baby while on this study. If you can become pregnant, you must have a pregnancy test before you enter this study and [if required] at regular intervals during the study. You and your partner must use contraception the entire time you are in the study. Acceptable methods of contraception are:
  - An intrauterine device (IUD)
  - hormone-based contraceptives (birth control pills)
  - condoms (male or female) must be used with another method, other than spermicide.
  - Complete abstinence from sexual activity that could result in pregnancy.
  - If you think you may be pregnant at any time during the study, tell the study staff right away. They will talk to you about your choices.

Female subjects of childbearing age will undergo a pregnancy test before each dosing section.

- Risk of loss of employment or violation of standard medical care practice: Please note that standard illicit drug testing does not typically test for psilocybin or psilocin. If you are tested for psilocybin or psilocin it may show on a urine / blood toxicology test for 1-3 days and hair toxicology tests for 90 days after ingestion.
- Loss of privacy

- For more information about risks and side effects, please ask the study leaders

### **Are there benefits to taking part in the study?**

There will be no direct benefit to you from participating in this study. However, the information that you provide may help health professionals better understand/learn more about psilocybin and/or psilocin therapy as a treatment for future patients.

### **What other choices do I have if I do not take part in this study?**

You are free to choose not to participate in the study. If you decide not to take part in this study, there will be no penalty to you. You will not lose any of your regular benefits, and you can still get your care from our institution the way you usually do.

### **How will my information be used?**

Researchers will use your information to conduct this study. Once the study is done using your information, we may share them with other researchers so they can use them for other studies in the future. When possible, we will only share de-identified data sets. Your data, including audio and video recordings, will never be accessible to the general public. We will not ask you for additional permission to share this de-identified information.

In instances where de-identification of data is not possible (e.g. audio and video recordings), transfers outside of UCSF will involve a legally binding, signed agreement to make sure that collaborators use appropriate procedures to protect your privacy. We will not share your name or any additional personal information. Any data that we share with collaborators will be destroyed when we finish the analysis. Your personal information will never be accessible to the general public.

**Research results:** There may be times when researchers using your information may learn new information. If this information might impact your health, medical care, and/or personal, this information may be shared with you. If this information is not relevant to your wellbeing, safety, or medical care, the information may not be disclosed.

### **Will information about me be kept private?**

Participation in research involves some loss of privacy. We will do our best to make sure that information about you is kept confidential, but we cannot guarantee total privacy. Some information from your medical records will be collected and used for this study. If you do not have a UCSF medical record, we will create one for you. Your signed consent form and some of your research tests will be added to your UCSF medical record. Therefore, people involved with your future care and insurance may become aware of your participation and of any information added to your medical record as a result of your participation. Study tests that are performed by research labs, and information gathered directly from you by the researchers will be part of your research records but will not be added to your medical record. Your personal information may be given out if required by law.

Safety concerns may also lead to a loss of privacy. The study team will need to break confidentiality for safety purposes, in case of threat of harm to self or others. Specifically, if the study staff are concerned that you are at risk of harming yourself/suicidal, a study doctor will evaluate you as soon as possible. You may need to stop participating in the study and be hospitalized.

If information from this study is published or presented at scientific meetings, your name and other personal information will not be used.

Authorized representatives from the following organizations may review your research data for the purpose of monitoring or managing the conduct of this study:

- Filament Ventures
- University of California
- Food and Drug Administration (FDA)
- Research Advisory Panel of California

This study is covered by a Certificate of Confidentiality from the National Institutes of Health. This means that the researchers cannot release or use information, documents, or samples that may identify you in any legal action or suit unless you give approval. They also cannot provide your information, documents, or samples as evidence unless you have agreed. This protection includes federal, state, or local civil, criminal, administrative, legislative, or other proceedings. An example would be a court subpoena.

There are some important things about the Certificate of Confidentiality that you need to know. The Certificate DOES NOT stop reporting that federal, state or local laws require. Some examples are laws that require reporting of child or elder abuse, some communicable diseases, and threats to harm yourself or others. The Certificate CANNOT BE USED to stop a sponsoring United States federal or state government agency from checking records or evaluating programs. The Certificate DOES NOT stop disclosures required by the federal Food and Drug Administration (FDA). The Certificate also DOES NOT prevent your information from being used for other research if allowed by federal regulations.

Researchers may release information about you when you say it is okay. For example, you may give them permission to release information to insurers, medical providers or any other persons not connected with the research. The Certificate of Confidentiality does not stop YOU from willingly releasing information about your involvement in this research. It also does not prevent YOU from having access to your own information.

### **Are there any costs to me for taking part in this study?**

No. The sponsor has agreed to pay for all items associated with this research study; you or your insurer will not be billed. The sponsor will provide psilocybin and pay for all of the assessments at no cost to you.

## **Will I be paid for taking part in this study?**

In return for your time, effort and travel expenses, you will be paid for completing all parts of this study. We will provide compensation for the Screening/Baseline session (up to 3 hours), Preparation Session (up to 3 hours), Integration Sessions (four sessions, up to 2 hours), and Phone Surveys (up to 1 hour, four appointments) at a rate of \$20/hr. You will be paid \$20 for each Dosing Session (up to 8 hours, four sessions), You may also receive up to a total of \$50 for the entire study for travel and parking for in-person appointments. In total, you can earn up to \$490 for participating.

## **What happens if I am injured because I took part in this study?**

It is important that you tell the study leader, Dr. Joshua Woolley, if you feel that you have been injured because of taking part in this study. You can tell them in person, call at 415 221-4810 x24117, or email [PsilocybinStudies@ucsf.edu](mailto:PsilocybinStudies@ucsf.edu)

**Treatment and Compensation for Injury:** If you are injured as a result of being in this study, the University of California will provide necessary medical treatment. The costs of the treatment may be billed to you or your insurer just like any other medical costs, or covered by the University of California or the study sponsor (Filament Ventures), depending on a number of factors. The University of California and the study sponsor do not normally provide any other form of compensation for injury. For further information about this, you can call the office of the Institutional Review Board at 415-476-1814.

## **What are my rights if I take part in this study?**

You can choose either to take part or not to take part in the study. If you decide to take part in this study, you can leave the study at any time. No matter what decision you make, there will be no penalty to you and you will not lose any of your regular benefits. Leaving the study will not affect your medical care in any way. You can still get your medical care from our institution.

We will tell you about new information or changes in the study that may affect your health or your willingness to continue in the study.

In the case of injury resulting from this study, you do not lose any of your legal rights to seek payment by signing this form.

## **Who can answer my questions about the study?**

You can talk to the study leader about any questions, concerns, or complaints you have about this study. You can reach Dr. Joshua Woolley at 415-221-4810 x24117 or by emailing [PsilocybinStudies@ucsf.edu](mailto:PsilocybinStudies@ucsf.edu)

If you wish to ask questions about the study or your rights as a research participant to someone other than the study leaders or if you wish to voice any problems or concerns you may have about the study, please call the office of the Institutional Review Board at 415-476-1814.



A description of this clinical trial will be available on [ClinicalTrials.gov](https://clinicaltrials.gov), as required by U.S. Law. This Web site will not include any information that can identify you. At most, the Web site will include a summary of the results. You can search this Web site at any time.

### CONSENT COMPREHENSION QUESTIONS

1. Participation in this study is voluntary and I may withdraw at any time.	T or F
2. I will be complete a series of interviews and questionnaires in order to determine my eligibility.	T or F
3. I will be complete four drug dosing sessions, each followed by an integration session.	T or F
4. The purpose of this study is to compare the effects of psilocybin to psilocin.	T or F
5. I can drop out of the study at any time, but it is recommended that I first consult with the study doctor to make sure it is safe.	T or F
6. Possible side effects of psilocybin and/or psilocin include anxiety, nausea, and headache.	T or F
7. How many times will you receive study drug?	_____

\*\*\*\*\*

### CONSENT

You have been given a copy of this consent form to keep.

You will be asked to sign a separate form authorizing access, use, creation, or disclosure of health information about you.

PARTICIPATION IN RESEARCH IS VOLUNTARY. You have the right to decline to be in this study, or to withdraw from it at any point without penalty or loss of benefits to which you are otherwise entitled.

You have read this information, which is printed in English. This is a language that you read and understand.

If you wish to participate in this study, you should sign below.

\_\_\_\_\_  
Date

\_\_\_\_\_  
Participant's Signature for Consent

\_\_\_\_\_  
Date

\_\_\_\_\_  
Person Obtaining Consent

**OPTIONAL CONSENT ITEMS**  
**UNIVERSITY OF CALIFORNIA, SAN FRANCISCO**

Please read each sentence below and think about your choice. If you agree with any of the statements below, sign and put today's date.

If you have any questions, please ask the researchers, talk to your doctor, or call our research review board at (415) 476-1814. No matter what you decide to do, it will not affect your care or participation in this study.

- 1. Someone may contact me in the future to see if I am interested in other research studies.**

\_\_\_\_\_  
Participant's Signature for Consent

\_\_\_\_\_  
Date